

### **Remarks**

Applicants appreciate the Examiner's indication that claims 2, 5-7, and 17 encompass allowable subject matter and that claims 18-20 are allowed. However, Applicants disagree that claims 1, 4, and 8-13 are anticipated or obvious as alleged in the Office action and respectfully traverse below the refusals of those claims. Applicants submit that the entire application is in condition for allowance and respectfully request withdrawal of all of the rejections in the Office action and allowance of the application.

#### **I. The Claims Are Not Anticipated**

The Office action alleges that claims 1, 4, and 8-11 are anticipated by Jansen et al. (US 6,378,714). Applicants disagree. Jansen does not disclose snap fit engagement parts on the transfer assembly disclosed in Jansen (which the Office action alleges corresponds to the clamp part in Applicants' claims) to secure the transfer assembly to the vial as alleged in the Office action. Indeed, Jansen specifically teaches away from the use of snap-fit engagement parts stating at C2:L30-32 that: "[s]nap on plastic collars, however, do not assure adequate sealing . . . and stoppers are required." This is a clear statement in Jansen that illustrates that Jansen does not disclose snap fit engagement parts to secure the transfer assembly to the vial and teaches those of ordinary skill in the art to avoid the snap fit engagement parts recited in claims 1, 4, and 8-11.

##### **A. Claim 1 Is Not Anticipated**

Applicants' claim 1 recites a clamp part that further comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial. Jansen does not disclose any part having snap-fit engagement parts thereon to engage the vial. Jansen

discloses a collar that must be crimped or deformed around the rim of a vial made from a malleable polymer that maintains its post-deformation shape. (See C2:L58-60; C6:L10-15.) The Office action offers the conclusory statement that the final product in Jansen comprises snap fit engagement parts because the collar fits “as though it were a snap-type connection.” (OA, p. 5.) The Office action provides no support for determining that the collar fits as though it is a snap-type connection, or that a collar that eventually fits onto the vial after crimping is a snap-fit part. However, in any event, the Jansen collar does not snap onto the vial. It must be crimped or deformed to fit the vial. A malleable part that is crimped into position and maintains its post-deformation shape is not a snap fit engagement part.

Further, as noted above, Jansen teaches away from snap fit parts to secure the transfer assembly to the vial and teaches those of ordinary skill in the art to avoid snap fit engagement parts and use a malleable collar instead. This derogation of snap fit parts made by Jansen demonstrates that Jansen’s malleable part that maintains its post-deformation shape is not a snap-fit part.

Jansen also fails to disclose a cover part that comprises an “upper wall” having a segment linked to the remainder of the cover part by a frangible link as this feature is claimed in claim 1 an embodiment of which can be seen for illustrative purposes in Fig. 2 A. The Office action *alleges* that Jansen discloses a cover part having a segment linked to the rest of the cover part by a frangible link (OA, p.2). However, the Office action fails to provide any argument that the alleged cover part disclosed in Jansen has an upper wall which has a segment that is linked to the remainder of the cover part by a frangible link as claimed by Applicants. Jansen’s failure to disclose such a part is another reason that Jansen does not anticipate the subject matter of claim 1.

As Jansen fails to disclose at least the noted features of Applicants' claim 1 and teaches away from the snap fit engagement parts feature, Jansen cannot anticipate Applicants' claim 1. The refusal should be withdrawn.

B. Claim 4 is not anticipated

Applicants' claim 4 depends from novel claim 1 and is not anticipated for at least this reason in addition to its other novel features. For example, Claim 4 further recites that the frangible link from claim 1 is further linked to the skirt wall of the cover part. The Office action states that Jansen shows in figure 2 a frangible link linked "to the skirt wall." (OA, p.2.) However, the Office action does not identify any alleged "skirt wall" in Jansen. As the Office action does not identify the allegedly anticipating structure, Applicants are hindered in preparing their response and the rejection is *prima facie* improper and should be withdrawn for this additional reason.

C. Claim 8 is not anticipated

Applicants' claim 8 depends from novel claim 1 and is not anticipated for at least this reason in addition to its other novel features. For example, claim 8 recites that a portion of the upper surface of the closure part is made of "a thermoplastic elastomer material." The Office action alleges that Jansen discloses a closure part formed of an elastomer and therefore that Jansen discloses a closure part formed of a thermoplastic elastomer. However, merely disclosing a part formed from an elastomer does not disclose a part made of a thermoplastic elastomer material. An "elastomer" is not necessarily a thermoplastic elastomer material.

D. Claim 9 is not anticipated

Applicants' claim 9 depends from novel claim 1 and is not anticipated for at least this reason in addition to its other novel features.

E. Claim 10 is not anticipated

Independent claim 10 is not anticipated by Jansen as alleged in the Office action. Jansen does not disclose, for example:

1. a cover part comprising an upper wall having a segment linked to the remainder of the cover part by a frangible link.

Jansen fails to disclose a cover part that comprises an "upper wall" having a segment linked to the remainder of the cover part by a frangible link as this feature is claimed in Claim 10 and embodiment of which can be seen for illustrative purposes in Fig. 2 A. The Office action states that Jansen discloses a cover part having a segment linked to the rest of the cover part by a frangible link (OA, p.2), however, the Office action fails to provide any argument that the alleged cover part disclosed in Jansen has an upper wall which has a segment that is linked to the remainder of the cover part by a frangible link as claimed by Applicants.

2. a clamp part comprising a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial.

Jansen does not disclose any part having snap-fit engagement parts thereon to engage the vial. Jansen discloses a collar that might be crimped or deformed around the rim of a vial made from a malleable polymer that maintains its post-deformation shape. (See C2:L58-60; C6:L10-15.) The Jansen collar does not snap onto the vial. It must be crimped or deformed to fit the vial. A malleable part that is crimped into position is not a snap fit engagement part.

Further, as noted above, Jansen teaches away from snap fit parts to secure the transfer assembly disclosed in Jansen to the vial and teaches those of ordinary skill in the art to avoid snap fit engagement parts and use a malleable collar instead.

As Jansen fails to disclose at least the noted features of Applicants' claim 10 and teaches away from the snap fit engagement parts feature, Jansen cannot anticipate Applicants' claim 10.

F. Claim 11 is not anticipated

Jansen fails to disclose a method including the features of:

1. providing a clamp part able to engage with the flange around the rim of the mouth opening of the vial by a resilient snap-fit engagement of a snap fit part of the clamp part underneath a downwardly facing surface of such a flange part.

As discussed above, Jansen fails to disclose, and instead teaches away from, snap fit engagement of the collar of the transfer assembly disclosed in Jansen with the vial disclosed in Jansen. Thus, Jansen fails to disclose providing a clamp part able to engage the vial by a resilient snap-fit engagement of a snap fit part of the clamp part.

2. engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement.

As Jansen fails to disclose, and instead teaches away from, snap fit engagement of the collar of the transfer assembly disclosed in Jansen with the vial disclosed in Jansen, Jansen also fails to disclose and indeed teaches away from engaging the clamp part with the assembly of vial and closure part by said snap-fit engagement.

It is clear in view of the forgoing that Jansen does not anticipate Applicants' claims and that the anticipation rejections in the Office action should be withdrawn.

## II. The Claims Are Not Obvious

The Office action alleges that claims 12-13 are obvious over Jansen in view of Py (U.S. 6,604,561). In this regard, the Office action first alleges that Jansen teaches all of the features of the claims with the exception of filling the container with a needle piercing the stopper and then sealing the opening with residual heat. Applicants disagree that Jansen teaches all of the features of the claims other than the exception noted in the Office action for at least the reasons noted above. The Office action next alleges that it would have been obvious to one of ordinary skill in the art to combine the heat sealing feature of Py with Jansen and that this would lead to Applicants' claimed invention. Applicants again disagree. The rejections are traversed below.

### 1. Claim 12 is not obvious

No combination of Jansen and Py disclose the features of the method of claim 12. The finding in the Office action that Jansen teaches all of the features of the claim with the exception of filling the container with a needle piercing the stopper and then sealing the opening with residual heat is incorrect. As all of the features of the claimed method are not present in the cited references, it is impossible to combine them to perform Applicants' claimed method and a *prima facie* case of obviousness has not been made.

In this regard, Jansen does not disclose providing a clamp part that comprises a peripheral skirt wall extending downwardly and having snap-fit engagement parts thereon to engage the vial. As discussed above, Jansen not only fails to disclose this feature, but teaches away from snap-fit engagement parts to engage the vial. Py does not provide this feature either. Accordingly, since all of the features of Applicants' claims are not present, the combination of Jansen and Py cannot even *prima facie* render claim 12 obvious.

In addition, Jansen fails to disclose an operable method for filling a vial by inserting a

filling needle, injecting a liquid, withdrawing the needle and engaging a cover part to cover a region of a closure part. Instead, Jansen concerns only the removal of a medicament from a vial by disengaging a closure part which breaks the frangible connections in Jansen and plunging the piercing member through a planar portion of an elastomeric stopper. (See C3-4) The method of operation of Jansen is incompatible with Applicants' claimed method. Combining Jansen with Py cannot rectify this deficiency as Py also does not disclose an operable method for filling a vial by inserting a filling needle, injecting a liquid, withdrawing the needle and engaging a cover part to cover a region of a closure part. Py simply discloses the use of a particular resealable stopper. Using this feature of Py in Jansen would not result in the subject matter of Applicants' claim 12.

Claim 12 is not obvious over Jansen in view of Py.

2. Claim 13 is not obvious

Claim 13 depends from claim 12 and further provides, prior to engaging the said cover part, directing a source of heat at the residual puncture hole in the upper surface of the closure part to melt the elastomer material in the immediate locality of the puncture and to thereby seal the residual puncture hole.

Claim 13 is non-obvious at least because its base claim 12 is non-obvious.

Moreover, it would not have been obvious to one of skill in the art to combine the heat sealing feature of Py with Jansen. Indeed, it would appear to be impossible to do so. The design of Jansen shields the pierced opening in Jansen. As can be seen in Fig. 2 of Jansen, the stopper body 32 that is pierced by the piercing member 42 is shielded from a potential heat sealing source by the body portion 78 of the of the piercing member and the filter 82. This apparent impossibility in combining the method disclosed in Py with Jansen means that one of ordinary

skill in the art would not combine these references in the manner set forth in the Office action and that one of ordinary skill in the art would not have found Applicants' claim 13 obvious over Jansen in view of Py.

In addition, to operate the piecing member of Jansen to pierce the elastomeric stopper one must remove the closure and break the frangible links holding the closure onto the transfer assembly. Accordingly, once the piercing member of Jansen has been operated to create a hole in the elastomeric stopper, it will not be possible to then engage the closure. Accordingly, it will be impossible to seal the residual puncture hole "prior to engaging the said cover part" as claimed in claim 13. Py does not overcome this deficiency in Jansen as Py does not contain any disclosure concerning a cover part or a method of filling a pharmaceutical vial utilizing such a cover part. Claim 13 is non-obvious for this additional reason.

### III. Conclusion


Applicants request reconsideration and withdrawal of the refusal in the present Office action in view of the foregoing. Applicants' claims are all in condition for allowance and such action is respectfully requested.

Respectfully submitted,

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